SRI/SURGICAL EXPRESS, INC.

NOV 1 8 2002

K023635

SUMMARY AND CERTIFICATION
SRI/SURGICAL EXPRESS, INC.,
SP™ REUSABLE SURGICAL GOWN

Class II (classification by the General Hospital and Personal use Device Panel)

Common Name: Surgical Gown

Classification Name: Surgical Gown

The purpose of this 510(k) submission is to obtain FDA clearance to market a reusable surgical gown manufactured with the W.L. Gore ASSIST™ medical fabric in the Critical Zones. The gown in this submission is substantially equivalent to the Sterile Recoveries, Inc. surgical gown as cleared under K920405. The results of safety and efficacy performance testing of the SRI/Surgical Express, Inc. reusable surgical gown as provided in this submission or as referenced in the W.L. Gore Product Master File MAF – 1138 are summarized below. The product is intended to be marketed sterile.

1. Biocompatibility: The ASSIST™ medical fabric used in the Critical Zones of this surgical gown complies with the requirements of ISO 10993-1 1997. Acceptable test results were obtained for the washed/dried/sterilized material using the specified test methodology. (Test results can be found in MAF – 1138)

2. Flammability: The ASSIST™ medical fabric used in the Critical Zones of this surgical gown complies with the requirements of 16 CFR 1610 *Standard for the Flammability of Clothing Textiles* (CPSC 1954), Class 1. (Test results can be found in MAF – 1138) The gown also meets requirements of NFPA 99-1999 regulations for non-flammable anesthetizing locations.

3. Barrier Performance: The ASSIST™ medical fabric used in the Critical Zones of this surgical gown achieved acceptable results throughout 125 wash/dry/steam autoclave cycles using the test methods prescribed in AATCC 42-Impact Penetration, and AATCC 127-Water Resistance: Hydrostatic Pressure Test. (Test results can be found in MAF – 1138.)

4. Physical Properties: The physical properties of ASSIST™ medical fabric were evaluated using various recognized industry standards following 125 wash/dry/steam sterilization cycles. There are currently no limits established for the physical properties evaluated, however conclusions can be drawn to substantiate that the results obtained are comparable to those of currently marketed surgical gowns. Testing was conducted using the following standards: *Spray Test*, ASTM D3776-96 *Standard Test method for mass per unit area (weight) of fabric*, ASTM D5035-95 *Standard Test Method for breaking force and elongation of textile fabrics (strip break)*, ASTM D5587-96 *Standard test methods for water vapor transmission of materials*, and IES-RP-CC003.3-93 *Garment system considerations for cleanrooms and other controlled environments – Helmke drum test for garment particulation.* (Test results can be found in MAF – 1138)

www.Surgicalexpress.com
formerly
STERILE RECOVERIES, INC.

12425 RACE TRACK ROAD
TAMPA, FL 33626

TEL 813-891-9550
FAX 813-925-8388

5. Sterilization: The gown in this submission has been validated to meet a Sterility Assurance Level of 10^{-6} using ANSI/AAMI/ISO 11134:1993 *Sterilization of health care products – Requirements for validation and routine control – Industrial moist heat sterilization.*

6. Care and Handling: The gown in this submission shall be processed in accordance with the requirements of ANSI/AAMI ST65: 2000 *Processing of surgical textiles for use in health care facilities,* the care and handling instructions from the manufacturer of the ASSIST™ medical fabric, and SRI/Surgical Express' internal quality system procedures to assure the safety and efficacy of the delivered product. No user instructions related to reprocessing the gown are required since the end-users are advised to return all soiled linen to SRI/Surgical Express, Inc. for reprocessing and sterilization.

Signature of Certifier: _____ Date: 10/22/02

Typed Name: Jack Hamilton Title: VP, Product & Process Engineering

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 8 2002

Mr. Jack A. Hamilton
VP, Product & Process Engineering
SRI/Surgical Express, Incorporated
12425 Race Track Road
Tampa, Florida 33626

Re: K023635
Trade/Device Name: SRI/Surgical Express SP™ Reusable Surgical Gown
Regulation Number: 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: October 22, 2002
Received: October 29, 2002

Dear Mr. Hamilton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Patricia Cicenia/for

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Applicant: SRI/Surgical Express, Inc.

510(k) Number: K023635

Device Name: SRI/Surgical Express SP™ Reusable Surgical Gown

Indications for Use:

Surgical gowns are devices that are intended to be worn by health care personnel during surgical or other medical procedures to protect both the surgical patient and the wearer from transfer of microorganisms, body fluids, and particulate material.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use _____ Over the Counter _____ Yes _____
Per 21 CFR 801.109

Signed for Clin

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K023635